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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,827	04/23/2001	Andrew J Garman	3764-78	3757

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EXAMINER
COUNTS, GARY W

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/27/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,827	GARMAN, ANDREW J	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,8 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the claims

The amendment filed on June 11, 2002 in paper No. 9 is acknowledged and has been entered.

Claim Rejections – 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 6, lines 6-9 in the specification. The applicant discloses the diffusion occurs on either side of the diffusion area. The applicant does not disclose that the diffusion is detected either side of the diffusion region. On page 7, lines 24-27 in the specification. The applicant disclose that the detector monitors the labeled component flowing past a single point. The applicant does not disclose that the diffusion is detected either side of the diffusion region. There is no description in the specification disclosing that the diffusion is detected either side of the diffusion region.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 3, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite because it is unclear how the inlet conduit is positioned so that it occupies the whole area of cross section that results in an area which is smaller than the length of the microfabricated conduit as indicated in Figure 4. Further, it is unclear how the liquid is delivered to both sides of the test compound. See also deficiency found in claim 8.

Claim 9, line 1 "diffusion is detected" is vague and indefinite. What diffusion is detected i.e. the diffusion of the test compound, or the ligand, or liquid?

Claim Rejections – 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Yager et al (WO 97/47390).

Yager et al disclose a microdevice comprising (1) a sample stream inlet; (2) an extraction stream inlet; (3) an extraction channel in fluid communication with sample stream inlet and extraction stream inlet for receiving a sample stream from sample stream inlet in adjacent laminar flow with an extraction stream from extraction stream inlet; (4) and two outlets which divide the laminar flow into a by-product stream outlet and a product outlet (page 3, line 17 to page 4, line 8). Yager et al also disclose the

use of a detector with the device to detect the presence of desired analyte particles (page 19, lines 14-23).

With respect to a diffusion region within the microfabricated conduit which defines an area which is smaller than the length of the microfabricated conduit as recited in the instant claims, Yager et al disclose a diffusion region which is variable (See Figure 2). Yager et al disclose that the sample stream and extraction stream form a laminar sample stream and laminar extraction stream within an extraction channel 7 and form a product stream with exaction channel 7. The product stream is formed after diffusion within the extraction stream. Therefore, Yager et al disclose a diffusion region within the conduit which defines and area which is smaller than the length of the microfabricated conduit.

Claim Rejections – 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yager et al (WO 97/47390) in view of Wu et al (US Patent 6,297,061).

See above for teachings of Yager et al.

Yager et al differ from the instant invention in failing to disclose introducing a liquid and introducing a mixture comprising a test compound, a receptor and a ligand.

Yager et al also fail to disclose detecting the diffusion of the test compound, or the ligand out of the diffusion region.

Yager et al disclose introducing in one inlet a mixture comprised of antigen, antibody and analyte. An extraction fluid is introduced in another inlet and the two streams join in adjacent laminar flow in joining a channel (col 7. lines 48-64, see also figure 7). This allows for the movement of different layers of fluid and particles next to each other in a channel without any mixing other than diffusion (col 1, lines 42-44) and also allows for simultaneous chemical reaction (col 1, lines 49-50). Yager et al also disclose detecting the diffusion of the test compound, or ligand out of the diffusion region. Yager et al disclose that competitive immunoassays can be incorporated into the method and that at the downstream end of the crossbar (conduit), the residual sample stream and the product stream divide into the two downstream arms of the device and that the product particles can then be detected in the product stream. The detection of the product particles can be performed by using optical, electrical, chemical, electrochemical or calorimetric analysis (col 2, lines 18-58). This allows for simultaneous chemical reaction, which facilitates the elimination of preprocessing of specimens containing particulate constituents, thus reducing the sample size and analytical time required (col 1, lines 49-53).

It would have been obvious to one of ordinary skill in the art to incorporate introducing an extraction fluid and a mixture as taught by Wu et al into the device of Yager et al because Wu et al teaches that this allows for the movement of different

layers of fluid and particles next to each other in a channel without any mixing other than diffusion and also allows for simultaneous chemical reaction.

It would also have been obvious to one of ordinary skill in the art to incorporate detection of immunoassay components as taught by Wu et al into the device of Yager et al because Wu et al shows that this allows for simultaneous chemical reaction, which facilitates the elimination of preprocessing of specimens containing particulate constituents, thus reducing the sample size and analytical time required.

Response to arguments

Applicant argues that Yager et al does not teach the diffusion region within the microfabricated conduit defines an area which is smaller than the length of the microfabricated conduit. This is not found persuasive because Yager et al disclose a diffusion region which is variable (See Figure 2). Yager et al disclose that the sample stream and extraction stream form a laminar sample stream and laminar extraction stream within an extraction channel 7 and form a product stream with exaction channel 7. The product stream is formed after diffusion within the extraction stream. Therefore, Yager et al disclose a diffusion region within the conduit which defines and area which is smaller than the length of the microfabricated conduit.

Applicant argues that Yager et al does not disclose or suggest introducing a liquid and introducing a mixture comprising a test compound and a receptor, or a test compound, a receptor and a legend into a diffusion region defining an area which is smaller than the length of the microfabricated conduit. This is not found persuasive because Yager et al disclose a diffusion region which is variable (See Figure 2). Yager

et al disclose that the sample stream and extraction stream form a laminar sample stream and laminar extraction stream within an extraction channel 7 and form a product stream with exaction channel 7. The product stream is formed after diffusion within the extraction stream. Therefore, Yager et al disclose a diffusion region within the conduit which defines and area which is smaller than the length of the microfabricated conduit.

Applicant further argues that Wu et al does not disclose or suggest differential diffusion. This is not found persuasive because the recitation of differential diffusion is not recited in the instant claims.

Conclusion

No claims are allowed.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
August 26, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
08/26/02